K123084

Elcam MEDICAL

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MAY 2 3 2013

Dec. 25, 2012

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

Submitter Information

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Submission contact person:

Aharon Cohen
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Device Classification

Proprietary Device Name:	Elcam High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds.
Common name:	Stopcocks and Manifolds for I.V.
Product Code:	FMG
Classification Name:	Stopcock, I.V. Set
Classification Regulation:	21 CFR § 880.5440
Regulatory Class:	II

Identification of the legally Marketed Predicate Devices

Elcam's legally cleared Stopcock and Manifold devices (K111016) are indicated for flow control and delivery of I.V drugs and fluids used in I.V procedures. Devices are intended for normal pressures of gravity feed, sampling and bolus injection.

Scientific Device Manufacturer, LLC's cleared SDM Angiographic Manifold devices (K96031) are intended for I.V medium and high pressure fluids injection, used in angiography procedures.

Above legally Marketed Devices used as substantial equivalence to Elcam proposed High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds (modified version of the legally cleared Stopcock and Manifold devices - K111016)

Device Description

Stopcocks and Manifolds are generally used for administration of fluids into the human body. There is a wide use of Stopcocks as flow controls and sampling sites in I.V sets, critical care applications and monitoring kits. Stopcocks are used individually or in the form of Manifolds, units comprised of several Stopcocks joined together ("gang").

High pressure Stopcocks and Manifolds are used in cardiac angiography and angioplasty procedures in which fluids are administered under pressure. These procedures require stopcocks and manifolds which are robust under high pressures.

The line of pressure resistant Stopcocks and Manifolds presented in this file includes four (4) products:

i. High Pressure (HP) Stopcocks
ii. Medium Pressure (MP) Stopcocks
iii. High Pressure (HP) Manifolds
iv. Premium High Pressure (PHP) Manifolds

Intended Use of Device

Elcam's High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds are intended to serve as flow control and delivery devices for I.V fluids injection to the patient's vascular system. The devices are indicated for medium and high pressure injection of fluids such as, but not limited to, fluids used during angiography and angioplasty and during interventional radiology and cardiology procedures. Devices indication for medium and high pressure does not preclude its use for low pressure procedures. The High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds are intended for single use only.

Safety & Effectiveness

The proposed and predicate devices are similar in design, materials of construction, components, intended use and labeling.
Based on the performance results provided (including test results and clinical data) and the analysis of similarities and differences presented above, Elcam Medical believes that the proposed device safe & effectiveness is substantially equivalent to the predicate device without raising new safety and/or effectiveness issues.

Rational for Substantial Equivalency

Substantial equivalency between the proposed devices, to its predicate devices was demonstrated by comparison in a tabular way of the intended use, indications, effectiveness, safety, performance and basic technological characteristics.

SE discussion:

#	Comparison parameter	**Proposed device: Elcam Disposable High Pressure Stopcock/Manifold**	**Elcam Disposable Stopcock/ Manifold**	**Scientific Device Manufacturer, LLC- SDM Angiographic Manifold**
1	**K No.**	**K123084**	**K111016**	**K960431**
2	**Owner**	**Elcam Medical A.C.A.L.**	**Elcam Medical A.C.A.L.**	**Scientific Device Manufacturer, LLC**
3	components materials	The device is composed of the following materals: Body: Polycarbonate LEXAN Handle: ACETAL-	The product is made of the following materials: Body: Former Lexan Handle: High Density	The product is made of the following materials: - Handle - Acetal

#	Comparison parameter	Proposed device: Elcam Disposable High Pressure Stopcock/Manifold	Elcam Disposable Stopcock/ Manifold	Scientific Device Manufacturer, LLC- SDM Angiographic Manifold
		ULTRAFORM High Pressure Rotator: Polycarbonate LEXAN O-Ring: Liquid Silicone Rubber (Apple Rubber)	Polyethylene	- O-Ring- Ethylene Propylene Terpolymer Rubber (EPDM) - Body-Polycarbonate - Handle plugs – Polyethylene
2	Pressure Rating	- HP Stopcocks – 1200 psi (82 Bar) - MP Stopcocks – 500 psi)35 Bar) - HP Manifold - 600 psi (41.3 bar) - PHP Manifolds - 800 psi (54.6 bar)	Pressure is up to 3 bar (44 psi)	Pressure Ranges 500 -1200psi
3	Performance parameters	Designed to withstand high pressure injections	Not designed to withstand high pressure injections	Designed to withstand high pressure injections
4	Integrity of materials and functionality after EtO sterilization	The materials and the product functionality are not affected by EtO sterilization process or as a result of aging over rated life time specification.	The materials and the product functionality are not affected by EtO sterilization process or as a result of aging over rated life time specification.	The materials and the product functionality are not affected by EtO sterilization process or as a result of aging over rated life time specification.
5	Biocompatibility standards	Tests performed according to ISO 10993	Test performed according to ISO 10993	Test performed according to ISO 10993
6	Performance Standards	Tests performed according to: ISO 8536-10 ISO 594-1 ISO 594-2	Tests performed according to: ISO 594-1 ISO 594-2	Unknown
7	Sterilization and sterile package integrity	Tests performed according to: ISO 11135-1, ISO 11607-1 and ISO 11607-2	Tests performed according to: ISO 11135-1, ISO 11607-1 and ISO 11607-2	Unknown

The above table compares similarities and differences between Elcam's High Pressure Stopcock/Manifold to legally cleared Elcam Stopcock and Manifold devices (K111016) and to Scientific Device Manufacturer, LLC- SDM Angiographic Manifold (K960431). The following summarizes the main tests performed to demonstrate substantial equivalence resulting from the use of different materials required for sustaining high pressure injection:

- High pressure performance tests for conformity to ISO 8536-10 standard
- Biocompatibility
- Integrity of materials and functionality after EtO sterilization
- Sterilization and sterile package integrity tests for conformity to ISO 11135-1, ISO 11607-1 and ISO 11607-2

Conclusion

The mentioned nonclinical tests and clinical use experience of Elcam's predicate legally marketed Disposable Stopcock/ Manifold demonstrate that the Disposable High Pressure Stopcock/Manifold is as safe, as effective, and performs as well as or better than the legally marketed devices identified in the K123084 submission.

Substantial Equivalence Statement

Based on the above, it is Elcam Medical's opinion that the proposed Elcam High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds are substantially equivalent in terms design principles, performance features and of safety & effectiveness to the legally cleared predicate devices : Elcam's Disposable Stopcocks/ Manifolds (K111016) and to Scientific Device Manufacturer, LLC's- SDM Angiographic Manifold (K960431), referred to in chapter 4 of this 510(K) submission executive summary document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 23, 2013

Mr. Aharon Cohen
Regulatory Affairs Manager
Elcam Medical A.C.A.L.
Kibbutz Bar-Am
D.N. Merom Hagalil
Israel 13860

Re: K123084
Trade/Device Name: Elcam High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: April 3, 2013
Received: April 25, 2013

Dear Mr. Cohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

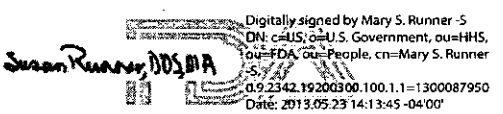
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
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Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K..... K123084

Device Name: Elcam High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds

Indications for Use:

Elcam's High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds are intended to serve as flow control and delivery devices for I.V fluids injection to the patient's vascular system. The devices are indicated for medium and high pressure injection of fluids such as, but not limited to, fluids used during angiography and angioplasty and during interventional radiology and cardiology procedures. Devices indication for medium and high pressure does not preclude its use for low pressure procedures. The High and Medium Pressure Stopcocks and High and Premium High Pressure Manifolds are intended for single use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Richard C. Chapman 2013.05.23 13:56:27 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123084